THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

GUIDELINES for ENVIRONMENTAL HEALTH SCIENCES CORE CENTER GRANTS

NEW AND COMPETING CONTINUATION APPLICATIONS

Updated September 1, 2005

TABLE OF CONTENTS

GUIDELINES FOR ENVIRONMENTAL HEALTH SCIENCES CORE CENTER GRANTS

I. INTRODUCTION

The National Institute of Environmental Health Sciences (NIEHS) invites applications from qualified institutions for the Environmental Health Sciences (EHS) Core Centers. These Centers are designed to build infrastructure in the field of environmental health sciences and environmental medicine. By facilitating the use of shared research resources that serve the research in the mission areas of the NIEHS, investigators who are associated with EHS Core Centers will be poised to lead the field in new and important directions. The mission of NIEHS is to improve human health by increasing understanding of how environmental exposures impact biological processes and systems that result in disease. The NIEHS carries out this mission by supporting research and professional development in the basic and applied sciences relevant to environmental health, environmental medicine, and environmental public health. In addition to understanding how environmental exposures affect human biology, it is critical for this information to be applied in order to reduce morbidity and extend longevity.

A P30 Core Center Grant is an institutional award, made in the name of a principal investigator, to support centralized resources and facilities shared by investigators with existing research projects. It is awarded competitively, initially for up to four years, and may be renewed for periods of up to five years. By providing a Center structure and Core resources, this support is intended to enhance the productivity of traditional research grants at the institution, focus investigators on environmental science issues relevant to clinical medicine and public health, and, thereby, improve the health of the community and nation. A Center Core Grant helps to integrate and promote research in existing projects and provides an administrative framework within one or several central themes; however, no funds are provided for direct support of research projects, except for pilot projects, recruitment of select new investigators, and research program development.

In contrast to past EHS Core Centers, the next generation of Core Centers is expected to bring their efforts to bear to a greater degree on translating environmental health research and related basic science results to public health and clinical arenas. One of the new goals of this program will be to develop opportunities and resources that support the integration of clinical research on patients and their care, public health research studying highly exposed population in the US and around the globe, and the disciplines of basic science. The Core Center, thus, is charged with creating effective teams at the institution(s) it serves to enhance existing programs in environmental health research and to build capacity in new and emerging areas which support or enhance these new directions in environmental health. The emphasis should be on fostering scientific excellence by providing resources unlikely to be attained by individual investigators, promoting collaborations among basic biomedical and clinical researchers, reaching out to innovative investigators in

complementary fields, and on facilitating cutting edge research that addresses public health issues in a timely manner.

In addition to direct research support services, the Center should provide career development for future research leaders. This can include training and mentoring to junior faculty in environmental health sciences, promoting interactions with established investigators in related disciplines, and helping young scientists and clinician-scientists to build foundations for careers in NIEHS-sponsored programs. Investigators and trainees are encouraged to interact with NIEHS program officials with the goal of promoting grantsmanship and eventual funding by NIEHS.

NIEHS expects that an EHS Core Center will:

- Provide intellectual leadership and innovation in environmental health sciences, environmental medicine, and public health;
- Stimulate integration of basic, applied, and clinical research in order to better understand the impact of environmental exposures on human disease
- Facilitate and develop new multidisciplinary and interdisciplinary research strategies to advance the field
- Incorporate novel technologies and methods into EHS research
- Serve as a source of information and expertise to the surrounding communities and stakeholders to further scientific collaborations and dissemination of research results
- Provide career development for future research leaders. Membership in the Center should help build identity in the fields of environmental health sciences, environmental medicine and public health through mentoring, training, and interactions with programs developed by NIEHS

This document provides information on NIH/NIEHS policies and procedures for EHS Core Center Grants (P30), including a general description, outline of essential characteristics, administrative requirements, facility core requirements, allowable budget items, application process, review procedures, and review factors.

II. GENERAL DESCRIPTION AND BASIC REQUIREMENTS

A. General Description

The EHS Core Center must be an identifiable organizational unit within a single university, medical center, or a consortium of cooperating institutions with a university affiliation. The EHS Core Center grant mechanism (P30) provides core support to foster integration, coordination, and interdisciplinary interaction and cooperation among a group of established investigators conducting high-quality research clearly related to the effects of environmental factors on human health. The NIEHS uses this mechanism to integrate and build upon existing programs and institutional resources such as university-wide facilities and services that encourage and enhance research on environmentally-induced disorders.

An EHS Core Center provides an administrative structure and an environment to strengthen and increase productivity and generate new ideas through organized interdisciplinary collaborative efforts. Its goal is to enhance the capabilities of existing programs in environmental health sciences, to assist with building the capacity for environmental health studies at institutions with less developed programs, and to support the development of future directions needed for the field to mature. As such, the EHS Core Center grant provides an added dimension that includes capability and potential for net accomplishment which will be greater than that possible by the support of individual projects. The EHS Core Center grant provides support for core resources and facilities to be used by Center investigators.

This support includes administrative and facilities personnel, equipment, supplies, and services. In addition, it provides limited funds for pilot projects, training, career development, and, optionally, community outreach. The EHS Core Center grant does not provide direct funding for ongoing research projects which are expected to be supported through other mechanisms, mainly individual research grants and program projects awarded by the NIH. Stipends and tuition for trainees – with certain exceptions for named new investigators and newly recruited investigators as described, below - are not provided by the EHS Core Center grant. Eligibility for an award is limited to domestic institutions.

B. Requirements

Environmental Health Science Grant Base

To qualify for an EHS Core Center the applicant institution must already have an identity in Environmental Health Sciences as defined as a substantial base of ongoing, independently supported, peer-reviewed research projects related to the study of environmental health sciences or environmental medicine/public health, a substantial portion of which should be supported by NIEHS (see page 9 for more details). This currently funded research base provides the major support for a group of investigators who would benefit from shared resources. The research base must exist prior to the submission of an application and will be a critical element considered during the peer review process. Focus, relevance, interrelationships, quality, productivity, and, to some extent, quantity, are all considerations in judging the adequacy of the research base.

Organizational Elements

1. An **Administrative Core** provides the leadership for scientific and programmatic activities of the EHS Core Center. This core oversees organizational, budgeting and reporting aspects of the Center.

2. **Facility Cores** are shared facilities that serve to enhance or make more cost effective the services, techniques, or instrumentation used by the investigators within the EHS Core Center. Cores should extend, support, and contribute to the work of the Center members. A

Center must have a minimum of two facility cores including an Integrative Health Sciences Facility Core.

3. A **Pilot Projects Program** is required and is considered to be an integral part of the support provided. This program provides modest support for new initiatives or feasibility projects for either new investigators or for established mid-level investigators who are moving into research areas of direct interest to the EHS Core Centers. Up to 25% of the budget can be allocated to the pilot projects program.

Five Essential Characteristics
These essential characteristics are explained in greater detail in the next section.

1. The **Center Director** is the principal investigator of the EHS Core Center and provides scientific and administrative leadership for the total program. The Center Director should work closely with thought leaders in a variety of disciplines represented in the Center to develop and implement a plan encompassing the vision and future directions of the Center.
2. A **strategic vision** and set of goals must be developed and described in the application to demonstrate how the EHS Core Center can effectively provide leadership and resources to on-going and new research in environmental health sciences, medicine and public health. The Center Director must provide the leadership to develop a strategy for how the Center will implement this vision and future directions during the project period.
3. Existence of a strong research base and **identity in environmental health sciences** is fundamental to establishment of a new, or continuation of an existing, EHS Core Center. Furthermore, a Center must be able to capitalize upon its research capacity and resources to advance significantly our understanding of its chosen scientific focus.
4. Emphasis on **career development** for environmental health scientists is essential. The application should address plans that will promote training of new investigators and bring new expertise into the area of environmental health sciences. Specify the plans to cross-train researchers in current techniques that are absent from the EHS Core center or individual research programs.
5. The **Institutional Commitment** at the applicant institution will be a major consideration in supporting the goals of the Core Center. The parent institution should recognize the EHS Core Center as a formal organizational component and provide documented evidence of space dedicated to the needs of Center, protected time to devote to Center activities, staff recruitment, dedicated equipment, or other financial support for the proposed Center.

Changes to the EHS Core Center Guidelines
As of September 1, 2005, the following changes are made to the Environmental Heath Sciences Core Centers:

1. **Name Change.** NIEHS is merging the NIEHS Core Centers and Marine Freshwater Biology Centers programs. The new combined program will be called the Environmental Health Sciences Core Centers Program (EHS Core Centers).
2. **Site visits**. NIEHS will no longer conduct site visits as part of the peer review process.

Program staff may decide to visit selected applicants to gain further information on which to base funding decisions after the formal review by study section.

3. **Increased focus on translation.** The program endeavors to focus investigators to a greater extent on clinical applications, translation, and multidisciplinary research that will speed research findings to clinical practice and environmental medicine.
4. **Dynamic structure.** In order to provide increased flexibility in organization and structure of the EHS Core Center, the Director may develop a dynamic structure which meets the on-going intellectual needs of the Center. This structure can change as intellectual needs change to accommodate new opportunities for collaboration. Research Cores are no longer required as organizational units in the Center. The proposed Center organization must include the required components outlined above, but beyond those requirements, no additional structure is imposed by NIEHS.
5. An **Integrative Health Sciences Facility Core** is required as one of the Center Facility Cores.
6. **Optional Community Outreach and Education.** Programs which focus on partnering with stakeholders in order to disseminate EHS Center research results are optional. EHS Core Centers which choose to include a Community Outreach and Education Core are eligible for additional $100,000 direct costs. Kindergarten through Grade12 (K-12) curriculum development and implementation is no longer allowed as a COEC activity.
7. **Page limitations.** NIEHS defines page limits for grant applications in these guidelines. For applicant convenience the NIEHS provides preformatted tables for necessary data (see page 31). Tables and appendix materials do not count towards the page limits.
8. **Essential Characteristics.** There are only five: Center Director, Institutional Commitment, Strategic Vision, Environmental Health Identity, and Career Development.

III. ESSENTIAL CHARACTERISTICS OF AN EHS CORE CENTER

The EHS Core Centers are a national resource for multidisciplinary approaches to problems in human environmental health. The Core Center should provide opportunities for collaboration among its members by promoting the sharing of resources and facilitating intellectual exchange. Research across many disciplines, including basic biological sciences, toxicology, epidemiology, exposure sciences, public health interventions, clinical sciences including patient care, community –based public health research should be promoted in order to facilitate translation of basic sciences to the bedside and in the development of strategies that will improve the health of vulnerable populations. They provide a stimulating, multidisciplinary environment that attracts both established and promising young investigators. As a national resource they form a network that fosters communication, innovation, and high-quality research. Interactions and collaboration across EHS Core Centers are encouraged. They are also a key source of expertise to the NIEHS when dealing with emerging issues in environmental health and a means for communicating environmental health issues to the public and elected representatives.

To promote this excellence, applicants must possess the following five essential characteristics described below.

A. Strategic Vision and Impact on Environmental Health

In order for an EHS Core Center to effectively provide leadership and resources to on-going and new research in environmental health sciences, medicine and public health, a vision and set of goals must be developed and described in the application. The Center Director must provide the leadership to develop a strategy for how the Center will implement this vision and future directions during the project period. The plan should describe the existing scientific research base, skills, technologies and other resources at an institution. This plan should describe how the Core Center will enhance ongoing projects, assist in the introduction of outstanding new projects, and promote collaborations, advances in technology, and progress in environmental health sciences. The Center Director must detail expected scientific outcomes including a description of the clinical application and/or impact of these outcomes on public health and environmental medicine.

Competing continuation applications must also describe the accomplishments of the Center in the preceding project period. The application needs to describe how the existing Center facilitated a leading role in environmental health at its home and associated institutions and enabled contributions to the field. It must discuss the specific aims and whether they were completed, how facilities were made available to the maximum number of qualified investigators, and the changes in resources that might have been made to accommodate altered user needs and/or increased demand. Measures of accomplishment include: publications and evidence of scientific advances that were aided by Center resources; pilot projects that led to NIH or other peer-reviewed research applications; new or improved tools, discoveries, or patented inventions (and documentation of the wide use of such tools); training and recruiting of new investigators who have advanced in their careers in environmental health; and, where applicable, outreach to affected communities and appropriate educational outcomes.

This plan must address the following critical elements:

- Theme – Provide the central theme(s) of the EHS Core Center and the likely supported research, resources, and relevance to environmental medicine. The theme may be broad or focused, depending upon the goals of the Core Center.
- Goals and directions
    1. Describe current and future directions for the Core Center in the forthcoming project period. How will the research supported by the EHS Center impact the understanding of environmental health sciences and, ultimately, public health? Describe the short, mid and far-term goals and measures of success. What are the likely advances expected in the field of environmental health, and how can these advances be applied to clinical medicine and public health? Describe any basic science advances that have been successfully translated to the bedside or plans in the next project period to enhance that translation. What expected widely-applicable research tools and scientific advances will emerge from the Center's emphasis?

2. Document how the Center will organize and lead the team towards these advances. Identify levels of risk for these goals, potential roadblocks to achieving them, and how the Center might respond to these challenges.

3. Competing continuation applications must also describe the accomplishments of the Center in the preceding project period and how it intends to build upon its successes. These accomplishments should be presented in three areas: basic science, clinical research, and public health science. The impact of Center-based science should be discussed in detail.

- Integration of investigators of multiple skills and talents – Outline steps the Center will take to promote multi-disciplinary studies and collaborations, especially among basic scientists and clinical researchers. What types of initiatives will stimulate the teams and attract high-caliber professionals? To what degree will high-risk / high-payoff research that may require long-term support be implemented?
- Building research capacity – Provide details on the special talents and resources that will be drawn to and built upon at the Center. How will these talents be harnessed and used to promote new collaborations and produce multi-dimensional teams to address more complex questions? Include a plan for bringing investigators into the Center from within and outside EHS. Describe academic and research partnerships that will be pursued by the Center to advance the goals and mission of the Center.
- Provide a plan to determine the need for services and instrumentation needs of the Center. Address the steps that will ensure that the Core Center proceeds at the cutting edge of technology and concepts. It is expected that the needs for facility cores may change with time. Include information on the process of re-evaluation of needs and implementation of changes.

B. Environmental Health Identity and Impact of Research Base

The EHS Core Center grant mechanism fosters interdisciplinary cooperation among established investigators conducting high-quality research in environmental health science. Therefore, existence of a strong research base in environmental health sciences is fundamental to establishment of a new, or continuation of an existing, EHS Core Center. Furthermore, a Center must be able to capitalize upon its research capacity and resources to advance significantly our understanding of its chosen scientific focus.

Environmental Health Sciences Identity will be determined by examination of:

- the scientific focus of the proposed EHS Core Center
- the subject matter of the grants and the minimum base of research grant support by held proposed members of the Center and are part of the application
- the experience and publications of the Center Director and members
- the structure and objectives of Facility Cores within the Center

- the manner in which the Center promotes interdisciplinary, inter-programmatic research
- evidence of other supported research, grants, or activities at the parent institution in environmental health sciences

At the time of submission of a new or competing continuation application, any institution or consortium wishing to qualify for the EHS Core Center grant must have an active, established program in basic, clinical, and/or epidemiological biomedical research in environmental health sciences. The existence of an ongoing, extramurally supported biomedical research base is a prerequisite for the establishment and continued support of a Core Center. A minimum of 5 active NIEHS-supported research grants from 4 distinct principal investigators is required at the time of application. Acceptable grant support includes R01, R21, R37, P01, P42, P50, Cooperative Agreement (U-grants) or Research Career Development Awards (K-grants). Training grants (e.g. T32), fellowships (F-awards), and R13 grants are not acceptable for the purpose of demonstrating the minimum research base. Multi-component projects such as program projects (P01) will be counted only once towards the minimum number of grants. At the time of submission of a new or competing application, these grants must minimally have two years of funding remaining, not including any administrative extensions, either with or without additional funds. Research grant support from NIH and sources other than NIH should be listed and will be considered in the determination of its suitability of focus on environmental health sciences. The research project should be (1) related to human health in areas where there is evidence or a strong rationale for the involvement of environmental factors in disease etiology or phenotypic expression, (2) the research is of outstanding quality, and (3) the funding entity used a peer review process of rigor comparable to that of NIH. Prior to submission of an application, the proposed Center Director must consult with Institute Staff regarding the adequacy of the research base.

Consideration in the peer review process will be given to the quality and impact of this research base. The reviewers will examine and place the greatest emphasis on grant support from NIEHS. They will look at the balance of support from other sources . The reviewers will also evaluate the Center's focus on an environmental health science theme, interrelationships among Center members, quality and productivity of the research programs, and demonstrated or potential interdisciplinary coordination.

Over and above the base of a sufficient number of high quality research grants, an effective EHS Core Center requires additional characteristics that must be demonstrated in the application. The following information is required in the application and will be evaluated by the peer review process.

1. Descriptive narrative of environmental health sciences research at the applicant institution(s) that emphasizes the focus, interactions, relationships, and scientific excellence of the projects and investigators and the impact on advancing scientific knowledge relevant to environmental health issues. Each project should be briefly described in a one-half page abstract and provided ion the appendix, which does not count towards the page limits of the applications.

2. For competing continuation applications, the effects and impact of the Core Center on research efforts including publications, subsequent funding, career advancement, and training

To assist in preparing the application, preformatted **Table A: EHS Research Base** is provided and can be downloaded from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm.

C. Center Director

Each applicant institution will specify a Center Director with adequate authority to be responsible for the organization and operation of the Center. The Director should be an experienced and respected individual who can provide scientific and administrative leadership for the total program. The Director needs to demonstrate understanding of environmentally related disorders at a level that will enable her/him to oversee high quality progress in clinical research that will translate into public health tools and advances. He/she must be able to coordinate, integrate, and provide guidance in the establishment of new programs, attract new and diverse investigators to the field, as well as direct Center resources to existing programs to maximize productivity. The authority of the Center Director should include the control of appointments to the Center. The Center Director should allocate a minimum of 20% effort. A Deputy Center Director must also be designated to serve in the absence of the Director, with other responsibilities described. The background and scientific and administrative expertise of the Center Director and the Deputy Director should be described fully in the application. In the case that the Center Director needs to be replaced, the Center must conduct a nation-wide search to fill the position. For competing applications, an assessment of past performance is required.

D. Career Development for Environmental Health Investigators

Emphasis on career development for environmental health scientists is essential. The application should address plans that will promote training of new investigators and bring new expertise into the area of environmental health sciences. Specify the plans to cross-train researchers in current techniques that are absent from the EHS Core center or individual research programs. Training and cross-training may include collaborations that will introduce a focus on human subjects and tissues into laboratory-based studies. These aspects of the program should be designed to prepare new investigators for an independent career in environmental health sciences.

The following activities are consistent with this aspect of the EHS Core Center.

New Investigator

Temporary salary support (up to 75%) and laboratory set-up costs can initially be provided in the application for a Named New Investigator in a specified area of research. The investigator can be a worker in the basic sciences, clinical research, or public health disciplines relevant to environmental health.

This investigator is eligible to compete for support for up to two years through the pilot project program. Subsequently recruited individuals are to be named by the Center Director and submitted for approval to the Center's Internal or External Advisory Board, as appropriate.

Newly Recruited Center Investigators
The EHS Core Center grant may provide partial salary support (up to 50%) for investigators newly recruited from outside the Center. This mechanism is intended to develop research programs by providing support for younger investigators who are at the beginning stages of their research careers, to add needed expertise to the Center structure, or to bring new methods and technologies into the environmental health sciences arena that enhance the Center's activities. Likewise, former graduate and postdoctoral students of Center members should not be considered for support unless it can be satisfactorily demonstrated that they have established independent research careers.

Funds awarded under this section may be used for salary, technical support, and equipment. The remaining salary support for the Newly Recruited Center Investigator must be derived from other than Center funds. For each investigator, the duration of support as a Newly Recruited Center Investigator will be limited to no more than two years. Specific individuals to be awarded Newly Recruited Center Investigator support need not be identified in the application, but the amount budgeted for this purpose should be declared, and, to the extent possible, the types of individuals sought and their expected roles in the Center described. Competing continuation applications should include a discussion of how these funds were used in the previous project period, in terms of who was recruited and how these individuals benefit the Center programs.

Career Development Activities in Clinical Research
The EHS Core Centers mechanism requires clinical and basic scientists with a broad range of skills to work together on a unified theme. Therefore, it presents a rich environment for young clinical investigators to be exposed to and develop additional research skills. Mid-level clinical investigators and scientists in other fields may also be attracted by opportunities in the Center to focus their attention on issues in environmental health sciences and environmental medicine. Financial support can be provided for training and mentoring of physician scientists to study environmental health issues that are relevant to the public health arena and clinical practice. In addition environmental health scientists can be supported to engage in activities which increase their understanding of clinical medicine. The objective of this activity would be to assist new investigators in progressing to more senior status and eventual NIEHS funding by enhancing their research skills and knowledge of the grants process. These activities can be constituted as an independent Facility Core otherwise these activities should be described as part of the Administrative Core.

The career development activities should be directed by an investigator with strong mentoring credentials who will devote a defined percent effort (5% suggested). To facilitate mentoring and multidisciplinary developmental activities, active involvement by senior investigators within the Core Center is strongly encouraged in an effort to match mentors with candidates. The plan for career development activities will be evaluated in terms of potential effectiveness in developing

the skills and research capabilities of new clinical investigators as reflected in the following required elements of the application:

- A discussion of how mentoring and the professional development of the investigators will be achieved, including their progression to more independent status
- A plan for monitoring the progress of the career development of selected investigators
- Examples of planned scientific enrichment activities for selected investigators including training experiences, mini-sabbaticals, special lectures, visiting scientist symposia, seminars, workshops, and short courses both at the parent institution or off-site.

In order to increase diversity in the student and faculty populations and the participation of individuals currently under-estimated in the biomedical, clinical, behavioral, and social sciences, applicants are encouraged to designate new and newly recruited investigators from the following groups: women, under-represented racial and ethnic groups; individuals with disabilities; and individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research.

Direct costs for career development activities should not exceed $50,000. Assisting new investigators in attaining independent status should be an objective of the Core activities. Sponsored participants should be encouraged to apply for NIEHS sponsored Career Development Awards, patient-oriented research grants, or other types of independent support. Contact with NIEHS program staff is encouraged at an early stage in submission of new applications.

E. Institutional Commitment

The Institutional Commitment at the applicant institution will be a major consideration in supporting the goals of the Core Center. The parent institution should recognize the EHS Core Center as a formal organizational component and provide documented evidence of its support to the EHS Core Center. Scientific personnel, dedicated effort, and institutional resources capable of supporting the research base must be available. Various combinations of personnel, staff recruitment, protected time to devote to Center activities, facilities, dedicated equipment, provision of space dedicated to the needs of Center, and financial obligations and commitments demonstrate institutional commitment.

The organizational status of the EHS Core Center and authority of the Center Director within the institution should be comparable to that of other units of similar importance and responsibility. The parent institution should provide assurance of its commitment to continuing support of the Core Center in the event of a change in directorship and have in place a well-defined plan for this eventuality.

The EHS Core Center is not intended to duplicate existing facilities or services at the participating institutions. Existing and new facilities will likely complement each other and the Core Center will need to interact extensively with these other units. Therefore, an important component of

institutional commitment is documentation of access, availability, and priority of members of the EHS Core Center to university-wide cores, equipment, infrastructure, and facilities at the institution(s).

IV. ORGANIZATIONAL AND OPERATIONAL ELEMENTS OF EHS CORE CENTERS

In order to provide increased flexibility in organization and structure of the EHS Core Center, the Director may develop a dynamic structure which meets the on-going intellectual needs of the Center. This structure can change as the intellectual needs change to accommodate new opportunities for collaboration and program development. Research Cores are no longer required as organizational units in the Center. The proposed Center organization must include the required components described below, but beyond those requirements, no additional structure is imposed by NIEHS.

The bulk of funding for a Core Center is intended to provide an administrative framework and a resource infrastructure for support of research activities of the Center. The Center itself is generally structured to consist of an administrative core, facility cores, a pilot projects program, and, optionally, and a Community Outreach and Education Core. In all cases, emphasis should be on development and support of shared resources or facilities which will benefit and strengthen the Center. Justification for establishment of a Core component should be based on ongoing and competitively funded research programs.

A. Administrative Core

It is expected that organization of the Administrative Core will provide a supportive structure sufficient to ensure accomplishment of the following:

- Coordination and integration of Center components and activities.
- Assessment of productivity, effectiveness, and appropriateness of Center activities.
- Determination of Center membership. Assessment of scientific opportunities and areas for collaboration among Center members.
- Interaction with other Centers, NIEHS, and other appropriate individuals, groups, or organizations.
- Organization of Center activities, such as retreats, invitation of consultants, meetings, and focus groups.
- Organization of the Internal and External Advisory Committees. Competing continuation

applications must document the functions and effectiveness of the External and Internal Advisory Committees.

- Record keeping of meeting minutes and measures of success including: use of EHS Core Center facilities, publications, pilot project awards, and new grant applications resulting from preliminary data enabled by the Center

In the case of an extended absence of the Center Director, the appointed Deputy Director will temporarily administer the Center. If the position of Director becomes vacant, a new permanent Director must be determined through a nationwide search for appointment as soon as possible by the institution. Deliberations regarding the appointment should involve the NIEHS staff and the ultimate recommendation of a new Director is subject to NIEHS approval. In general, the NIEHS will require that the new Director have scientific and administrative qualifications comparable to those of the original Director.

The administrative structure must include an Internal Advisory Committee (IAC), selected from Center members and core leaders of the Center, to assist the Center Director in making scientific and administrative decisions. In the application, the committee must have a clearly outlined role in evaluating relationships of all projects to overall objectives of the Center, assessment of progress of ongoing research programs, and continual reevaluation of use of Center resources. Either this committee or the External Advisory Committee is encouraged to provide input on requests for pilot projects. The IAC may elect to add ad hoc experts to assist in decisions on pilot projects.

An External Advisory Committee (EAC) to the Center Director must also be established. The External Advisory Committee should consist of a group of four to seven scientists, including a chairperson, at least 75% of who are from outside the grantee institution. It is inappropriate for any individual associated with the Center or with administrative responsibility for any aspect of the Center to serve on the EAC. The function of this committee is to assist in evaluating the merit of the Center programs, the relevance and importance of the individual components to the objectives of the Center, the impact of the training and career development activities of the Center, the effectiveness of communications within the Center, the effectiveness of the pilot project program and, the value and anticipated contributions of proposed new Center initiatives and, optionally, as an alternative to the IAC on decisions for funding pilot projects. Likewise, the EAC is expected to make recommendations concerning the removal of core support from projects no longer considered fruitful or relevant. The EAC must meet at least once annually. The EAC may be supplemented by ad hoc members knowledgeable in particular areas or segments of the program being reviewed. The EAC, as part of its review responsibilities may evaluate the pilot project program and its accomplishments, if it is not involved in the decision making for this program.

The Administrative Core must also identify one individual with appropriate fiscal expertise who will function as the business manager for the Center. This individual may be located at the Center level, the Department level, or be an institutional business official, but it is important that this one person be responsible for fiscal aspects of the Center grant and be directly involved in its nonscientific management. This person will also serve as the point of contact with the Grants

Management staff of NIEHS. The business manager should also be a participant at the meetings of the IAC to assure that institutional concerns are recognized in the melding of interests of the EHS Core Center and the individual projects. While budget formulation and planning undoubtedly will begin with the Center Director in collaboration with scientific staff, the business manager must be involved deeply in the process and must give final approval. The diversity of support requires that the institution evaluate such things as equipment on hand versus that requested for core facilities, the usage of core facilities by individual research projects, and documentation on equipment maintenance costs borne by individual grants and core center grants. This information should be available to the NIEHS on request in preparation for periodic reviews of Center progress or site visits. The Center will be given ample advance notice of these events.

In addition to its responsibilities for fostering communication and cooperation within the Center and developing program goals which will optimally exploit its resources, interests, and expertise, the Administrative Core must provide a framework through which the Center can work with the NIEHS and with other EHS Core Centers to meet national environmental health research needs. The goals of these activities are to work collaboratively with other EHS Core Centers in strategies to enhance research collaborations, public health progress, and/or community outreach and education goals. These goals can be included in the EHS Core Center Plan.

To facilitate communication and dissemination of information and review of problems and national needs in the environmental health sciences, meetings of all Center Directors and appropriate NIEHS staff are held annually. Each Center institution and the NIEHS act as host institution on a rotating basis. These meetings are scheduled well in advance and provide a forum for discussion of program accomplishments, needs, etc. by each Center Director and the Director, NIEHS, and his/her staff.

B. Facility Cores

The major function of the Center grant is to support Facility Cores which have multiple users. These cores should be designed to furnish groups of Center investigators with techniques, services, or instrumentation in a manner that will enhance the research in progress, consolidate manpower effort, and contribute to cost effectiveness. Only one type of Facility Core is proscribed: an Integrative Health Sciences Facility Core, which is described, below. The number and type of the other Facility Cores may vary within the constraints described in this section depending on the needs of the Center.

Facility cores for the EHS Core Center should be unique and are not to duplicate services or facilities that already exist at the parent or collaborating institutions. University-wide facility cores providing services in areas relevant to environmental health research have become more widely available at many research centers. EHS Core Centers should utilize existing facility cores where appropriate and describe in the application how members of the EHS Core Center would receive priority access, favorable cost arrangements, and training on unique technologies. If facilities within a university-wide facility are not sufficient to meet the needs of the EHS Core Center, then

the applicant is to provide information on the existing facilities and on how the Center and greater university facility plan to partner. Proposed Center facility cores that appear to replicate services already available at the applicant institution will not be allowed without extensive justification.

Facility cores should draw on Center research needs, including, but not limited to: animal use and transgenics, imaging, tissue culture, pathology support, statistical support, oligonucleotide synthesis, analytical chemistry, proteomics, bioinformatics, exposure assessment, and handling of human tissue specimens. Establishment and continued support for Facility Cores by an EHS Core Center application must be justified on the basis of use by independently funded Center investigators. At least three investigators with independently funded projects with demonstrated need for such a core service form the minimum required research base to establish a core facility. Although use of these cores by pilot projects cannot contribute to the research base for a core, their utilization by pilot projects is encouraged. Use of core facilities by projects funded by research and development contracts will be evaluated on an individual basis. In general, use of Core facilities by contracts must be paid in full from the contract funds, not from the EHS Core Center grant funds.

Additionally, the minimum of three funded investigator users does not in itself provide sufficient justification for establishment of a Facility Core. To aid in review of the application, documentation of actual or expected use should be provided in a standard format, for example, by using **Table C: Facility Core Use** (http://www.niehs.nih.gov/centers/appguide.htm) for each Facility Core. Define the actual or expected level of use of the Facility Core in terms of low, mid, or high.

The application must provide the total operating budget for each Facility Core together with the percentage of support requested from the Center Grant. User logs or similar information should be maintained and made available on request to the NIEHS in order to validate the extent of use and degree of sharing. In the case of new proposed Centers or new Facility Cores within an existing Center, similar information regarding anticipated use of the Cores should be provided.

Each Facility Core must have a designated leader who will be responsible for core activities. The application should explain the organization and proposed mode of operation of each core. It should include a plan for prioritizing investigator use of the core as well as a definition of qualified proposed and potential users. This definition need not be too narrow, since some limited use of a core might be an enticement to established investigators in other fields to lend their expertise to the field of environmental health. If the Facility Core also is used to train investigators in special techniques, the extent of and approach to this training should be included. The use of the core for training purposes is encouraged.

Although Facility Cores are meant to provide services for Center members, they also play an important role in developing new methodologies, adapting instrumentation for Center needs, and educating Center members of the value and utility of services and methods. Limited funds can be designated to support these aspects of the Facility Cores and discussion of how these activities will be performed should be included in the application.

Integrative Health Sciences Facility Core

The Integrative Health Sciences Facility Core is required and should be designed to facilitate the translation of basic research findings into clinical or public health applications. This Core should provide new and critical resources and will be a vital component of the progression of environmental health sciences from the bench to the bedside and the affected communities. It is expected that the concepts and goals of environmental medicine will be integrated into the range of activities that the greater Core Center undertakes.

This Core is to be designed to support collaborative efforts among basic scientists, clinical researchers, and/or public health practitioners by:

- Providing services and access to instrumentation and technologies that foster integration of basic science, public health research including epidemiology and intervention studies, and patient-oriented clinical research.

- Supporting research to improve early detection, prevention, and/or therapy for environmentally – related disorders.

- Support partnerships between researchers and community based organizations which impact on conduct of clinical and public health research

Among its functions, the Integrative Health Sciences Facility Core may provide access to well-characterized patients and control subjects for research projects. Related services can include study subject recruitment and retention activities, and follow-up by mail, phone, or in-person to gather needed data for research projects. Clinical services may include clinical laboratory or other assessments, pathology services collection, processing and long-term storage of human tissue samples, blood, urine of other biospecimens, and preparation of questionnaires or other assessment tools. The IHSFC can facilitate and support partnerships between study populations or communities, health care providers or others. Description of services, equipment, and other activities of this core need to be well documented. Procedures for collecting, storing, and distributing biological samples, should be described in the application. Partnerships with other units, investigators, or service providers at the institution that support these type of activities (e.g. General Clinical Research Centers) are encouraged and letters of support should be included in the application. As with other Facility Cores, the application should include a description of the types of research projects (with specific examples) and clinical trials that use or will use the core and the benefits that will extend to other research activities.

NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b)

therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research.

C. Pilot Projects

Inclusion of a pilot projects program in EHS Core Centers is required. NIEHS considers this component of the EHS Core Centers to be an integral part of the support provided. Up to 25% of the direct cost budget for each year should be allocated to the Center Pilot Projects Program to support short-term research projects to explore the feasibility of new areas of study and which leads to collection of sufficient data to pursue support through other funding mechanisms. Investigators are encouraged to consult with NIEHS program staff before submission of new grant applications based on pilot project-supported data. Pilot projects are primarily intended to:

- Provide initial support for new investigators to establish new lines of research.
- Allow exploration of possible innovative new directions representing a significant departure from ongoing funded research for established investigators in environmental health sciences.
- Stimulate investigators from other areas of endeavor to apply their expertise to environmental health research and environmental medicine.
- Foster opportunities that meet goals set out in the EHS Core Center Plan.

Pilot project support is <u>not</u> intended for:

- Extension of projects by established investigators for which it would be appropriate to submit a research project grant application
- Funding or supplementing ongoing research of an established investigator.

A plan to solicit, review and administer pilot grants for basic or clinical biomedical, epidemiological, educational, or behavioral research must be included in the Administrative Core and a separate budget including the total request for pilots must be submitted. Criteria for review of pilot studies must be developed and included in the application. These are to include the eligibility criteria for the applicants (such as young investigators, unfunded aspiring clinician scientists, etc) and details of the program structure and goals. Input from the EAC or IAC supplemented by scientists with relevant expertise is strongly encouraged. The application needs to be clear on how the Pilot Project Program assists in fostering new research in environmental health sciences, as directed by the EHS Core Center's Strategic Vision.

Multiple pilot studies of approximately 1 – 2 years duration are permitted. Typically, this support is non-renewable. Records of meetings and decisions on pilot project need to be maintained by the Administrative Core and made available on request from the NIEHS.

The results of pilot projects also are to be maintained and readily available on request to the NIEHS or the EAC. The subsequent results of pilot projects – e.g. R01 applications (both funded and unfunded); publications; advancement of junior investigators - also need to be tracked by the Administrative Core in order to evaluate the success of the program.

In competing continuation applications, review of this program will be based on the record of accomplishments, the management of the program, and an assessment of overall potential needs and opportunities. Therefore, in general, a competing continuation application should also include:

- An historical overview of the Pilot Project program during the last program period.
- A description of the management of the program.
- A listing of all pilot projects which were supported during the last project period, giving the title, amount awarded, investigator, a brief description of the project and, if known, the results and outcomes such as, grant submissions, funding, and publications. To assist with the collection of this information, we are providing **Tables E1: Pilot Projects and Outcomes and E2: Grant Details for Pilot Projects** (http://www.niehs.nih.gov/centers/appguide.htm).

D. Community Outreach and Education Core

NIEHS Core Centers have the option to develop and sustain community outreach and education activities. The objective of the Community Outreach and Education Core (COEC) is the translation of research information into tools and resources for various professional and public stakeholders. Therefore, each Center that chooses to develop a COEC, must demonstrate that the objectives, activities, and products are aligned and integrated with the research strengths and focus of their Center.

The overarching goal of the COEC is to develop the field of environmental health outreach by promoting the widespread dissemination and institutionalization of outreach and education projects that are effective in translating environmental health science to target audiences. This is done in part by encouraging open dialog and peer review of these strategies, approaches, and models. COEC activities should be based in sound outreach and evaluation theory and research, as it relates to the field of environmental health, in order to improve clinical and public health.

Programs developed by COECs will lead the field of environmental health outreach and education at the local and national level. To this end, the goals of the COEC are to:

- Develop partnerships with stakeholders to translate and disseminate EHS Core Center science.
- Work with community-based organizations, disease advocacy groups and other local, state, or regional partners to enhance the dialogue on environmental health issues in their regions.
- Develop and implement appropriate outreach and educational programs to increase awareness and understanding of environmental health research being conducted at the EHS Core Centers.
- Evaluate outreach models, disseminate results at local and national levels and promote models for national implementation.

To meet these goals, it is essential for COECs to state clear and measurable objectives, possess appropriate expertise to fulfill its stated objectives, identify specific environmental problems, demonstrate alignment to research strength and focus of the Center, identify existing and future partners, prioritize short, mid and long-term activities to be implemented, list and describe expected products, state anticipated impacts and their significance for environmental public health, and define evaluation tools to measure the impact of core activities.

For the purposes of the NIEHS Core Center Program, there are three target audiences of interest: Community, Policy-makers, and Public Health and/or Health Care Professionals. COECs may select more than one target audience, but are required to choose only one.

Target Audience: Community

Types of activities the COEC may include one or more of the following:

1. Convene public environmental health awareness forums or workshops in the community. When hosting such forums, there should be a defined goal and measurable outcome, other than the number of participants attending.
2. Host and organize disease prevention and intervention programs, especially those that are community-based. When hosting such forums, there should be a defined goal and measurable outcome, other than the number of participants attending.
3. Create informational programs that address environmental health concerns or issues in the community, e.g., radio or television shows, museum exhibits, and educational programs at community, youth, science, or nature centers. Such programs should have a well defined dissemination and evaluation strategy before being developed.
4. Evaluate local outreach models, disseminate findings, and promote dissemination of models for national implementation.
5. Establish environmental health research programs for high school students that nurture their interest in science and public health. As high school students begin considering areas of study in college, having research experience in a lab can be a great opportunity to determine if its what they really want to pursue. COECs can work with Center investigators to establish a summer research program where they are mentored by graduate and senior research staff, present research findings, and learn more about environmental health.

Target Audience: Public Health and/or Health Care Professionals
Types of activities the COEC may include one or more of the following:

1. Develop and implement educational programs in environmental health science for health care providers (physicians, nurses, pharmacists). COECs may wish to develop and offer Continuing Education workshops for health care professionals who may wish to learn more about environmental health issues without actually becoming involved in research.
2. Create tools and resources for health care providers (physicians, nurses, pharmacists) that can be used and disseminated nationally. Health care providers may require easy to use tools to remind them of environmental health issues when interacting with patients in the home or the office.
3. Create and nurture national networks of public environmental health outreach specialists to have a national impact. COECs should build upon the outreach and education expertise around the United States. Thus, COECs may consider establishing a network of outreach and education specialists, not necessarily within the EHS Core Centers Program, to communicate environmental public health messages. This network should also interface with national disease organizations. Such networks and collaborations should focus on identified problems, research methods, special populations, or communities.

Target Audience: Public Health Decision Makers
Types of activities the COEC may include one or more of the following:

1. Provide advice and information to stakeholder groups who participate in designing and implementing health policy.
2. Create materials based on research that can be used to educate decision makers about environmental health issues.
3. Organize meetings addressing defined environmental health issues.
4. Participate in committees at the local and national levels in order to translate the scientific findings of the Center into public health and regulatory programs.

Should a Core Center choose to support a COEC

- The COEC is required to establish a Stakeholder Advisory Board to strengthen the bi-directional interaction between the Core Center and its partners. The purpose of this advisory group is to ensure Center understanding of community and other stakeholder needs, as well as to insure more effective dissemination of Center research in appropriate venues. Advisory Boards lead to increased trust between the research center and stakeholders The Center should develop a specific plan and set of integrated activities for COEC, particularly with respect to the Center's defined community and target audience. COEC must be a logical outgrowth of the scientific focus of the Center and exhibit the potential for mutual benefit due to interactions with Center investigators.
- COECs must possess the appropriate expertise for the identified target audience and outlined activities. It is important that COECs be directed by staff trained in public health, outreach and education, and other relevant disciplines at a Master's or Doctoral level. A well-designed COEC will be led by professionals who can apply academic theory and

models to outreach programs at the EHS Core Center and disseminate successes of COEC activities in appropriate forums (peer reviewed journals, conferences, etc.). COEC team skills and training should encompass abilities to conceptualize, develop, conduct and evaluate integrated programs, and disseminate outcomes and impacts in peer reviewed journals and/or at professional conferences (presentations, posters, workshops, etc).

- Collaborations among COECs in EHS Core Centers are desirable. Support of collaborations can be from NIEHS/NIH or by other agencies and foundations. Funding from sources outside NIEHS is advantageous to sustain high-quality COEC efforts.
- COECs are encouraged to collaborate with NIEHS staff within the Division of Extramural Research and the Office of Communication and Public Liaison in developing printed and audiovisual educational materials. These outreach activities must be identified as programs supported by the NIEHS Core Center. All COEC-produced materials must be submitted to the Community Outreach Resource Center.
- Support for appropriate staff positions, travel, equipment, and supplies for this activity is allowed.
- It is important to note that COEC is not intended to include human subject research, epidemiology, clinical trials, clinical services delivery, or community-based research. All research projects should be contained within research cores and be separately peer reviewed and funded. However, COEC may be useful, for example, as a means of establishing a productive relationship with a community-based organization, which could subsequently form the foundation of a research grant application. In such cases, appropriate COEC proposals may be considered for pilot project funding. The program should not go beyond public and community education about reducing environmental disease risk and/or hazard exposure recognition as the COEC is not intended to give medical, legal, political, social, or economic advice.
- *Kindergarten-Grade 12 curriculum development is no longer allowed as a COEC activity.*

V. ALLOWABLE BUDGET ITEMS

The appropriate OMB cost principles as modified by the Federal Regulations applicable to these grants and the PHS Grants Administration Manual and Grants Policy Statement govern the general rules of allowability, allocability and reasonableness of costs. These guidelines will be a part of the terms and conditions under which these awards are made. It is important to recognize that, even though a cost may be allowable, it is the responsibility of the applicant to adequately justify the inclusion and amounts of all items for which funding is requested. Should an award be made, it is NIH practice to limit escalation; accordingly, an adjusted escalation factor will be utilized in computing future year costs.

To aid in review of the application, it is recommended that separate budget pages be prepared for each of the following elements:

1. Administrative Core
2. Each Facility Core
3. Pilot Projects
4. Optional COEC Core

A. Professional Personnel Salaries

For all of the categories of personnel listed below, the requested percentage of an individual's salary may not exceed the percentage of effort devoted specifically to meeting actual Center responsibilities. The total percentage time devoted to Center-related activities, paid or unpaid by the Center, should be stated. Documentation substantiating this level of effort must be included in the application and levels of effort should be described in each appropriate part (core) of the application.

1. Senior Leadership Personnel
   This category includes individuals who have responsibility for overall direction of the entire Center (e.g., Center Director and Deputy Director). The Center Director should dedicate a minimum of 20% total effort to the Core Center.

2. Facility Core Leaders
   This category includes the designated leaders, directors, or coordinators of the identified Facility Cores of the application. Program directors or leaders are eligible for salary support under this category for the time and effort they devote to carrying out functions such as research planning, supervision, coordination activities, core administration, and staff training. In addition to these leadership activities, program directors should be active participants in high-quality research such as being a principal investigator on a funded research grant. A description of activities and time estimates for all core directors' functions must be included in the proposal. Core directors will not be funded unless they direct bona fide programs and are judged by peer reviewers of the Center grant to be appropriate leaders of such programs. Individuals identified as Core Leaders or other senior leadership personnel must be designated as key personnel on the application.

3. Center Investigators
   No salary support for research activities is allowed except for Named New Investigators and Newly Recruited Investigators. Appointment as a Center investigator is an indication of active participation in the Center's interdisciplinary and coordinated approach to research on problems in environmental health. The Center investigator benefits from the appointment by being able to use core facilities, etc., and by participating in the interactive framework of the Center. The Center benefits from the scientific and intellectual input of

these investigators. The anticipated result will be a synergistic effect on research programs in the Center due to the existence of the Center grant.

4. Administrative and Technical Support Personnel

    a. Salaries and support for Center administrative and clerical personnel, such as the business manager, COEC staff, secretaries, and clerical support staff, may be provided. These costs should not duplicate or replace costs included in the institution's indirect cost rate. Justification for clerical support should describe fully the duties to be performed for each requested position and include information on how many other clerical positions are in the Department or Center, how many are employed by Center investigators, and explain the source of funding for each. *Note.* The level of support provided under this section cannot exceed 10% of direct costs.

    b. Salary support for technical personnel or positions to be filled in Facility Core units may be included. However, the time and salary of all technical and support personnel must be related to a Facility Core, or to support a Named New Investigator, or a Newly Recruited Center Investigator. If the individual functions primarily in providing a Facility Core function, justification for the position should be made in a table such as **Table C: Facility Core Use** which can be downloaded from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm. Appropriate acknowledgment will be verified by the Grants Management staff of NIEHS prior to Center application review. Technical support personnel may receive up to 100% support from the Center, subject to merit review. As a general rule, funds for support of shop personnel and mechanical maintenance should be included as a part of the institutional base for indirect cost calculations and are unallowable as direct costs to the Center. However, in highly unusual circumstances, costs for specialized core facilities which would not otherwise be available at the Institution without the existence of the Environmental Health Sciences Core Center may be allowed with proper justification and documentation. Prior to including such costs in the application the Center Director is strongly encouraged to discuss proposed costs with program and grants management staff of the NIEHS.

5. Trainees and Career Research Support
   Allowable costs for Career Development Activities in Clinical Research include salary support for the Core Leader and other participating senior investigators and staff, travel costs for new investigators, and costs for courses, seminars, workshops, and other activities directly related to the development plan. These funds may be used for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; (d) statistical and computational services including personnel and computer time. All expenses must be directly related to the proposed research career development program.

B. Equipment/Facilities

This category includes items for broad use in the Center within a Facility Core. Center grant funding is particularly useful for purchases and operation of large items of equipment which are difficult to justify in individual grant applications. When equipment is requested, similar items already available must be reported and a clear justification of the function for the new ones must be provided. The application should provide a list of potential users and projects, giving grant numbers if possible. The applicant must also provide, on the budget justification page, any duplicate requests which have been made for funding the equipment requested. Co-funding of expensive items of equipment is encouraged. The requested budget for the equipment should be in the Facility Core providing this service and not in Administrative or Pilot Project Program budgets.

C. Supplies

Consumable supplies, such as office materials, glassware, animals, chemicals, etc. may be requested, provided they are items used in common by Center personnel and serve to reduce the cost requirements for individual projects. The requested budget for supplies should be in the appropriate Administrative, Facility, or COEC Core providing this service

D. Travel

Appropriate travel requests include:

1. Travel of the Center Director, one other Center scientist, and an administrator to meetings with other EHS Center Directors or to other center facilities pursuant to administration of the Center.

2. Travel of scientific, technical, or administrative staff for training that would enhance the quality of a Facility or COEC Core unit operation or travel required to maintain the operation of a Facility or COEC Core unit. However, this must be focused, active, intensive training such as a specific course or workshop as opposed to a session at a national meeting or the equivalent.

3. Travel of Named New Investigators and Newly Recruited Center Investigators to relevant scientific meetings is permitted. Travel of other scientific staff to scientific meetings or for the purpose of dissemination of research results is not allowed. These costs are more appropriately borne by individual research grants.

All travel should be budgeted within the appropriate core unit.

E. Consultants

Travel and expenses for named consultants and members of the External Advisory Committee and their associated costs may be included. Support of consultants must be fully justified in terms of program needs. Cost of visiting scientists and seminar speakers in conjunction with enrichment activities are allowable, but all items must be fully itemized and justified.

F. Pilot Projects

As described previously, pilot projects are required and up to 25% of the direct costs of each year's budget are to be allocated to their support.

Non-Competing and Competitive Renewal applications should clearly delineate and report the specific allocations of grant funds to the pilot projects program for each year of funding, providing details as described earlier.

G. Other Expenses

Maintenance contracts on general use equipment, duplication costs for annual reports, computer rentals, etc. may be included if fully justified by the application. Requests for funds for equipment maintenance must specify what items are to be maintained, the total yearly cost for maintaining each item, the main users of the item, any other source requesting funding for maintenance of these items, and the amount being contributed from other sources. Publication costs and page charges related to research results of pilot projects are allowed. However, publication costs and page charges for dissemination of other research results by staff investigators are not allowable. Costs of developing, printing, and distributing educational materials are permissible to the extent authorized by PHS policy. Inclusion of a statement recognizing that the document was created in whole or in part with PHS funds should be included on publications. The requested budget for these expenses should be in the appropriate Administrative, Facility, or COEC Core providing this service and not in a Research Core budget.

H. Alterations and Renovations

Funds for alteration and renovation of existing facilities may be requested so long as required for operation of Center programs. However, NIEHS Staff should be consulted as early as possible in the planning of these facilities for special instructions, limitations, etc. Funds for alterations and renovation will not be allowed unless there will be at least two years remaining on the grant at completion of the proposed alterations and renovations.

I. Contracts and Consortium Arrangements

These are, in general, allowed but require special budgetary and reporting format. The NIEHS staff should be consulted prior to submission for special instructions.

J. Items NOT Fundable under a P30 EHS Core Center Grant

1. Direct support of individual research projects.

2. Salary and support for central institutional administrative personnel usually paid from institutional overhead charges.

3. Salary and support for administrative activities such as public relations.

4. Travel of investigators, other than Named New Investigators and Newly Recruited Center Investigators, to scientific meetings.

5. Page and publication charges for staff investigators.

K. Budget and Duration Limitations

New Applications
New or first-time applicants can apply for up to four years of support. New applications are limited to requests for no more than $500,000 in direct costs in the first year; $600,000 in direct costs in the second year; $700,000 in direct costs in the third year; and $800,000 in direct costs in the fourth year. An additional $100,000 direct costs in each year may be requested if a COEC is to be included. Requests for budgetary increases in years 2-4 must be well justified scientifically and financially, and these justifications will be specifically assessed by the EHS Review Committee. Budgetary increases in years 2-4 of new awards are not automatic, and it is therefore important for applicants to provide sufficient information on proposed expansion of research, facility, and/or COEC cores, pilot projects, etc., to permit evaluation. Both the duration and amount of support are subject to peer review evaluation and NIEHS policy considerations.

Exceptions to the budget limits are only allowed with written approval from NIEHS. Examples of such programs are: Core Center support for population-based studies, enhancement of outreach activities, funding of up to $25,000 for a one-time evaluation of an immediate environmental health crises, or, in certain cases, purchase of specialized equipment or instrumentation.

Competing Continuation Applications
Competing continuation (renewal) applicants can apply for up to five years of support. For renewal budget requests for five years of support, annual direct costs are limited to $1.0 million or $1.1 million if 10% of the budget is allocated for COEC. Both the duration and amount of support are subject to peer review evaluation and NIEHS policy considerations. Exceptions to this limit may be made in consultation with NIEHS officials for special emphasis programs. Some examples of such programs would be: Core support for population-based studies, enhancement of outreach activities, funding of up to $25,000 for a one-time evaluation of an immediate environmental health crises, or, in certain cases, purchase of specialized equipment or instrumentation. Prior consultation with the NIEHS staff is necessary for any such exception.

Expanded Authorities: NIEHS Center Grants are administered under the provisions of Expanded Authorities as specified in the following excerpt from the NIH Grants Policy Statement: http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600128.
In addition to the above- referenced summary of authorities routinely granted to all NIH awards, NIEHS has elected to EXCLUDE the P30 EHS Core Center Grants from the provision of automatic carryover authority.

In accordance with the NIH Grants Policy Statement, unobligated funds of 25 per cent or less of the total amount awarded in the current year award (excluding any funds restricted by the terms of the award) CANNOT be automatically carried over without prior NIEHS approval. Requests for carryover of unobligated funds will be reviewed by NIEHS to ensure funds are necessary for completion of the project; additional information, including a detailed categorical budget, must be submitted from the grantee as part of this review. If it is determined that some or all of the unobligated funds are not necessary to complete the project, the NIEHS may take one of several actions: 1) approve the request for carryover of a portion of the available funds, 2) use the balance to reduce or offset NIH funding for a subsequent budget period, or 3) a combination of items 1 and 2, above. **The Financial Status Report must be submitted and accepted by the Office of Financial Management before approval is granted.**

Center directors have considerable flexibility to re-budget funds between budget areas in response to changing research needs. The center director may increase any budget category by up to 25 per cent over the level approved by peer review without prior NIEHS approval.

Subcontract F & A costs do not contribute to the direct cost caps listed above.

Grantees may access the following website (http://era.nih.gov/userreports/pr_due.cfm) to determine when a progress report is due. The list is updated on or around the 30th of each month. In addition to this website, email reminders are sent to the principal investigator.

VI. APPLICATION PROCESS

A. Speaking with Program Staff

Interested investigators are strongly urged to consult with NIEHS program staff prior to preparation of an application. It is recognized that preparation of applications for large, multi-investigator grants requires a substantial investment of time, effort, and resources by the Center Director and the applicant institution. During initial conversations, the NIEHS staff can discuss the potential applicant's plans for an EHS Core Center and whether or not they are consistent with the guidelines for Centers and mission responsibilities for NIEHS. The base of peer-reviewed research support at the proposed Center is a likely item to be discussed with NIEHS staff as it will be of interest to reviewers. If appropriate, alternate support mechanisms may be suggested.

The potential applicant is strongly advised to submit a Letter of Intent. This letter should include a title of the proposed application, a concise description of the proposed Center, the name, address, and telephone number of the Principal Investigator, and the identities of other key personnel and participating institutions. Although a Letter of Intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains is helpful in planning the review of applications. Advice given by the staff should not be misconstrued as authorization for award. Staff will not evaluate or discuss merit of scientific aspects of the proposal.

The Letter of Intent should be received 30 days prior to the next submission date of February 15, 2006, by:

Leslie Reinlib, PhD
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
79 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-4998 Fax: (919) 316-4606
E-mail: reinlib@niehs.nih.gov

B. Preparation of Applications

This section supplements the Information and Instructions for Application for Research Grant (Form PHS 398 rev 9/04) which is included in NIH grant application kits. Because these application forms are designed primarily for individual research grants, additional information is required when used for Center Grants. Except as modified in the following sections, the general instructions should be followed. Please arrange the Main Body of the application (section 1.l,

below) according to the following list and remain within the page limits for each section as follows:

Page Limits

1. Strategic Vision and Impact on Environmental Health – 25 pages
2. Environmental Health Identity and Impact of Research Base – 25 pages
3. Center Director - 5 pages
4. Career Development – 10 pages
5. Institutional Commitment – 5 pages
6. Administrative Core – 25 pages
7. Each Facility Core – 25 pages
8. Pilot Projects – 25 pages
9. Optional COEC – 25 pages

Tables

We are providing the following tables to assist in preparing applications. Applicants can download the tables, which have been preformatted to facilitate their completion, from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm.

Table A: Grant Support
Table B.1: Center Members
Table B.2: Key Personnel Effort
Table C: Facility Core Use
Table D.1: Publications resulting from Center involvement
Table D.2: Publications resulting from Pilot Program funding
Table E.1: Pilot Projects and Outcomes
Table E.2: Grant Details for Pilot Projects that were successful in competing for grant funding

New Applications

The following information should precede the main text of the application.

1. The Face Page and page 2. Item 2 of the face page should be "Environmental Health Sciences Core Center Grant." A title should be chosen to correspond to the major theme of the Center.

2. Complete Table of Contents, page 3. (Remember to number all pages consecutively, renumbering the printed application kit page numbers, if necessary).

3. Complete consolidated budget for the entire Core Center (page 4). Continuation pages may be used if needed to list all personnel.

4. Consolidated, or total, budget for the proposed project period (using page 5 of the application kit).

5. Distribution of Professional Effort on this application, arranged in a tabular format such as that shown in **Table B.2: Key Personnel Effort.**

6. A separate budget for each core unit or activity must be included using duplicates of application kit pages 4 and 5. ("First 12-month period" and "All Years of Support Requested") All proposed costs must be fully justified for both the 12-month and future years budgets as indicated in the PHS 398 instruction sheet. In addition, the budget justification should specify the proportion of each investigator salary that is being requested under each of the investigator categories, i.e., Core leader. Similar justifications should accompany requests for technical personnel.

7. **Table C: Facility Core Use** (or similar) should follow budgets for each Facility Core.

8. A listing, by Principal Investigator, of all grant support held by Center investigators that is related to environmental health research and currently active. Each grant should be listed only once. Information to be included is: Principal Investigator, complete grant, number, title, total project period, total amount, current annual amount. NIEHS-supported grants should be listed first, followed by other NIH grants, other federal contracts and cooperative agreements, and other sources. Individual postdoctoral fellowships should not be listed.

9. **EHS Identity**: Describe each project briefly in a one-half page abstract and provide the collection in the appendix. We are providing **Table A: EHS Research Base** to assist in preparing their application. Applicants can download the table, which has been preformatted to facilitate completion, from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm:

    a. Number and amount of all other NIEHS support.
    b. Number and amount of other NIH (excluding NIEHS) support.
    c. Number and amount of other Federal (excluding NIH) support.
    d. Number and amount of all non-Federal support.

10. The page entitled "Other Support" should be filled out for each person described as Key personnel.

    Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel.

11. Biographical Sketches: The program director/principal investigator should be first, followed by other key personnel in alphabetical order. Research support for the last three

years should not be included as part of the biographical sketch. Bio sketches are limited to two pages. Bio sketches for other personnel, such as Center Members, may be provided in the Appendix.

12. The Main Body of the Application. The introduction should concisely present the proposed theme(s), strategic vision, and background information leading to the request for Core Center support. It should also include a description of the aims and objectives of the Center, benefits to be achieved by funding as a Center grant, special program resources, and overview descriptions of activities and functions of each Facility Core, and COEC emphasizing areas of coordination. This should be followed by more detailed presentations of the Administrative Core and the other Core Units, providing the information elaborated in the preceding sections of this Guide.

13. We are providing **Table A: Grant Support; Table B.1: Center Members; Table C: Facility Core Use** to assist in preparing their application. Applicants can download the table, which has been preformatted to facilitate completion, from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm.

Competing Renewals

Instructions for new applications pertain also to competing renewal applications. In addition, however, competing renewal applications must contain a progress report covering the entire project period of the Center since the initial application or the most recent competing renewal application. This progress report should contain an overall executive summary of the most significant advancements of the Center as well as the complete progress of each of the cores.

In addition to the Tables listed above for New Applications, we are providing for Competing Continuation (renewal) Applications, **Table D.1: Publications Resulting from Center Involvement; Table D.2: Publications Resulting from Pilot Project Funding; Table E.1: Pilot Projects and Outcomes; and Table E.2: Grant Details for Funded Pilot Projects** to assist in preparation of the application. Applicants can download the tables, which have been preformatted to facilitate completion, from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm.

In addition to the information requested in new applications, provide:

1. A list showing changes, if any, of responsible investigators since the most recent competitive review. We are providing **Table B.1: Center Members** to assist in preparing this portion of the application. Applicants can download the table, which has been preformatted to facilitate completion, from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm.

2. The rationale for changes, if any, in percent effort and salaries charged to the Center for each investigator, including technicians and other support personnel.

3. A list of discontinued or modified Core Units, with an explanation for discontinuation or modification.

4. A list of all publications and completed manuscripts which have acknowledged Center support and resulted directly from Center-stimulated research during the period covered by the progress report. Do not list publications from prior project periods. We are providing In **Table D.1: Publications Resulting from Center Involvement** and **Table D.2: Publications Resulting from Pilot Project Funding** to assist in preparing the application. Applicants can download the table, which has been preformatted to facilitate completion, from the NIEHS website at http://www.niehs.nih.gov/centers/appguide.htm.

Use of Human Subjects and Animal Welfare

Current NIH policy requires approval indicated on items 4 and 5 of the face page of the PHS 398 form for all projects involving the use of human subjects and vertebrate animals whether new, competing renewal, or supplemental. Additional information is required for EHS Core Center grants, however. For projects funded in whole or in part through federal sources, please provide, as an attachment, a separate list of each individual project involving human subjects and a list of each project involving vertebrate animals in which Center personnel are involved. As a minimum, this list should include the investigator's name, grant or contract number, title of project, assurance number, and date of the most recent institutional review and certification. Letters from the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) should be included that state that any research (pilot studies or other non-NIH reviewed research) performed under this grant will obtain IRB and IACUC approval.

Policy Regarding the Inclusion of Women and Minorities in Clinical Research Studies.

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103 43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59: 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, volume 23, number 11, March 18, 1994.

Investigators may also obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

If research involving human subjects is proposed in the Center application that has not been reviewed according to the current policy, either because it was begun prior to January 1, 1991 or because it is funded by non-NIH funds, provide a description of the study, the population involved, and information related to whether or not the results are expected to be generalizable regardless of gender or race. This will assist the NIEHS in obtaining more complete information as to the make-up of study populations in research supported in any way by the Institute.

Application Submission

Applications for all types of NIEHS Core Center grants--new, competing renewal, and supplemental--competing for funds in a given fiscal year are submitted on a single receipt date announced through a solicitation in the NIH Guide to Grants and Contracts. In general, the schedule shown below will apply:

Guide Announcement	September 2005
Letters of Intent Receipt Date	February 15, 2006
Receipt Date	March 15, 2006
Initial (Scientific) Review	July, 2006
Council Review	September 18-19, 2006
Start Date	April 1, 2007

This schedule and single receipt date allows new applicants sufficient lead time to prepare an application and to plan for implementation if funded. Applicants for competing continuations will have approximately seven months between Council review and the start date. It also permits responsible financial management by the Institute of its Centers Program.

The original and three copies of the completed application should be mailed to the Division of Research Grants. Addressed labels are included in the Form PHS 398 application kits. In addition to those copies submitted to the Division of Research Grants, please send two informational copies, under separate cover, to the Program Administrator (See item IX below). These copies are useful to the staff for planning purposes.

In addition, any appendix material should be mailed directly to the Scientific Review Administrator, Environmental Health Sciences Review Committee. This should be done following acknowledgment of receipt and assignment of the application. Fifteen collated copies of appendix material are requested.

The Center for Scientific Review (CSR) has the responsibility of assigning an application to the appropriate NIH Institute. The Institute assignment is based on the scientific goals of the entire program. The CSR, in consultation with the Institute, makes the decision as to whether or not a

given application fits established criteria for a Center grant. All applications for EHS Core Center grants will be reviewed by CSR staff upon receipt for completeness and by NIEHS staff for responsiveness to the requirements set forth in this document. Applications found to be incomplete or non-responsive will be returned to the applicant organization without scientific review.

VII. NEW CHANGES FOR SUBMISSION

As of September 1, 2005, the following changes are implemented to the Environmental Heath Sciences Core Centers:

1. **Name Change.** NIEHS is merging the NIEHS Core Centers and Marine Freshwater Biology Centers programs. The new combined program will be called, the Environmental Health Sciences Core Centers Program (EHS Core Centers).
2. **Site visits**. NIEHS will no longer conduct site visits as part of the peer review process. Program staff may decide to visit selected applicants to gain further information on which to base funding decisions after the formal review by study section.
3. **Increased focus on translation.** The program endeavors to focus investigators to a greater extent on clinical applications, translation, and multidisciplinary research that will speed research findings to clinical practice and environmental medicine.
4. **Dynamic structure.** In order to provide increased flexibility in organization and structure of the EHS Core Center, the Director may develop a dynamic structure which meets the on-going intellectual needs of the Center. This structure can change as intellectual needs change to accommodate new opportunities for collaboration. Research Cores are no longer required as organizational units in the Center. The proposed Center organization must include the required components outlined above, but beyond those requirements, no additional structure is imposed by NIEHS.
5. An **Integrative Health Sciences Facility Core** is required as one of the Center Facility Cores.
6. **Optional Community Outreach and Education.** Programs which focus on partnering with stakeholders in order to disseminate EHS Center research results are optional. EHS Core Centers which choose to include a Community Outreach and Education Core are eligible for additional $100,000 direct costs. Kindergarten through Grade12 (K-12) curriculum development and implementation is no longer allowed as a COEC activity.
7. **Page limitations.** NIEHS defines page limits for grant applications in these guidelines. We are providing preformatted tables to assist in preparing the application. Tables and appendix materials do not count towards the page limits.
8. **Essential Characteristics.** There are only five: Center Director, Institutional Commitment, Strategic Vision, Environmental Health Identity, and Career Development.

VIII. REVIEW PROCEDURES

A Center grant application assigned to the National Institute of Environmental Health Sciences will be reviewed for scientific merit by the Environmental Health Sciences Review Committee (EHSRC).

The final review and recommendation on all applications assigned to NIEHS is made by the National Advisory Environmental Health Sciences Council. The NAEHS Council is the primary body for determining the significance of the application to the program goals and mission of the NIEHS.

IX. REVIEW FACTORS

The primary consideration for a Center grant application is the ability of the Center structure and personnel to bring together quality research activities into an interactive, multidisciplinary operation. A successful application will demonstrate quality scientific research.

Review Criteria for the Overall P30 EHS Core Center

The **Overall Center** will be evaluated based on the following criteria:

- The overall quality and productivity of the team, especially as it relates to the interactive, collaborative research opportunities in basic, applied and clinical research stimulated by the Center. For competing continuation applications, the evaluation will be based on information submitted since the previous competitive review. For new applications, this will be based on the history of prior collaborative efforts.

- The impact and productivity of the Center through publications by Center investigators, conferences, new funded research grants in environmental health sciences, new collaborations with other organizations, etc. For competing continuation applications, this evaluation will be based on information submitted since the previous competitive review. For new applications, this will be based on the history of prior collaborative efforts.

- The career development strategies employed by the Center for future research leaders in environmental health sciences, environmental medicine, and public health.

- The degree to which the Center has established itself as a recognizable entity in the fields of environmental health sciences and environmental medicine and public health.

For **competing continuation applications**, the following additional criteria will be included.

- Evidence that important discoveries or major accomplishments have occurred since the last review.

- The effectiveness of the Center in developing novel technologies and building upon research opportunities.

Essential Characteristics of the EHS Core Center

Strategic Vision and Impact on Environmental Health

In order for an EHS Core Center to effectively provide leadership and resources to on-going and new research in environmental health sciences, medicine and public health, a vision and set of goals must be developed.

The Strategic Vision and Impact on Environmental Health Sciences will be evaluated based on the following criteria:

- The adequacy of the current and future directions of the Center, including how the research supported by the Center will impact the understanding of environmental health sciences and, ultimately, public health.

- The adequacy of the Center's plans for promoting multi-disciplinary studies and collaborations, especially among basic scientists and clinical researchers.

- The adequacy of the Center's plans for building research capacity. The adequacy of the Center's plans for bringing investigators into the Center from within and outside environmental health sciences.

For competing continuation applications, the following additional criteria will be included.

- The adequacy of the Center's accomplishments in the preceding project period and how it intends to build upon its successes.

- Success in the translation of basic science advances to the bedside or to public health, and the adequacy of the plans to enhance that translation in the next project period.

Environmental Health Sciences Identity

The Environmental Health Sciences Identity will be evaluated based on the following criteria:

- The capacity of the Center to foster interdisciplinary, state-of-the-art, innovative research that can be expected to result in important discoveries or major scientific advances in the chosen areas of scientific focus.

- The adequacy of the size and breadth of the research grant base that is **directly** relevant to environmental health sciences research and to the theme of the Center, placing special emphasis on NIEHS-supported grants.

- The degree to which the Center takes advantage of the capability of its research base to maximize scientific productivity, particularly through interdisciplinary coordination and collaboration.

For competing continuation applications, the following additional criteria will be included.

- The progress and achievements of the Center since its last competitive renewal.

- Changes in the environmental health sciences research orientation of the Center and their impact on the Center since the last competitive review.

Center Director

The Center Director will be evaluated based on the following criteria:

- The ability of the Center Director to provide scientific and administrative leadership and direction.

- The authority and effectiveness of the Center Director in appointing new members to the Center and in discontinuing membership status, when appropriate.

- The qualification of the Deputy Director to serve in the absence of the Director.

Career Development for Environmental Health Investigators

The Career development of Environmental health Investigators will be evaluated based on the following criteria:

- The adequacy of the Center's plans for recruiting and training new investigators.

- The adequacy of the Center's plans for cross-training of junior and established investigators. The adequacy of the plans to train researchers to learn current techniques that are absent from their research programs.

- The adequacy of the Center's plans for mentoring junior investigators so as to foster their research careers; the quality of the proposed mentoring plan; and the adequacy of the plans for monitoring the progression and development of new and established investigators.

Institutional Commitment

There must be a strong institutional commitment to the Center. The following review criteria will be included:

- Evidence of the level of institutional commitment to the Center.

- Evidence that the presence, stature, and effectiveness of the NIEHS Center represent an established organizational component within the institution.

- The adequacy of the specific resources provided by the institution such as personnel, appropriate facilities, financial support, and other forms of support that reflect the level of the institution's commitment to the continuing development and success of the Center.

For competing continuation applications, the following additional criteria will be included.

- The degree to which specific commitments and plans for the Center from the previous competitive reviews were addressed.

Administrative Core

The administrative structure of a P30 EHS Core Center should include, in addition to the Director, a Deputy Director, a business manager, an Internal Advisory Committee, and an External Advisory Committee. Individuals in senior leadership positions should provide intellectual, administrative, and scientific leadership for the Center and are critical to its overall effectiveness and evolution. These individuals should be in place and committed to a defined per cent effort.

The Administrative Core will be assessed based on the following criteria:

- Evidence that the administrative structure is designed for effective management of the Center.

- The adequacy of the Center's plan for initiating, continuing, and discontinuing individual membership in the Center.

- The adequacy and per cent efforts of administrative staff of the Center in terms of their qualifications and contributions to the specialized needs and conduct of the Center's research activities.

- The adequacy of the Center's plans for how the Internal Advisory Committee and External Advisory Committee will be used and the expertise of the advisory committees.

- The appropriateness of the budget in relation to the Center.

For competing continuation applications, the following additional criteria will be included.

- The past performance of each senior leader in overseeing the planning, integration, and coordination of research involved in the Center.

Facility/Service Cores

The Facility/Service Cores will be assessed based on the following criteria:

- The Core's utility to the Center. Each Core must support a minimum of at least 3 investigators with independently funded projects.

- The quality of the facility or service provided.

- The cost effectiveness of the service.

- The qualification of the personnel involved.

Integrative Health Sciences Facility Core

In addition to the criteria outlined for the Facility/Service Cores, the Integrative Medicine Facility Core will also be assessed based on the following criteria:

- The adequacy of the services offered for technologies that will foster the integration of basic science, public health research including epidemiology and intervention studies, and patient-oriented clinical research.

- The adequacy of the research support to improve early detection, prevention, and/or therapy for environmentally – related disorders.

- The adequacy of the Core's plan to supports partnerships between researchers and community based organizations that will impact on the conduct of clinical and public health research.

Pilot Project Program

The Pilot Project Program will be assessed based on the following criteria:

- The adequacy of the plans for the review process used by the Center to distribute funds for pilot projects.

For new applications, the following additional criteria will be included:

- The adequacy of the Center's plan to use pilot project funds to test innovative ideas of importance to environmental health sciences.

- The adequacy of the Center's plan to use the Pilot Project Program for filling gaps in research areas relevant to the scientific focus of the Center.

For competing continuation applications, the following additional criteria will be included.

- Whether pilot project funds have been used to test innovative ideas of particular importance to environmental health sciences.

- The past effectiveness of the Pilot Project Program in filling gaps in research areas relevant to the scientific focus of the Center.

- The degree to which pilot project funds have been used to stimulate scientifically productive interactions and collaborations.

Community Outreach and Education Core (COEC) (optional)

The overarching goal of the COEC is to develop the field of environmental health outreach by promoting the widespread dissemination and institutionalization of outreach and education projects that are effective in translating environmental health science to target audiences. This is done in part by encouraging open dialog and peer review of these strategies, approaches, and models. COEC activities should be based in sound outreach and evaluation theory and research, as it relates to the field of environmental health, in order to improve clinical and public health.

<u>K-12 curriculum development is NO LONGER allowed as a COEC activity.</u>

The Pilot Project Program will be assessed based on the following criteria:

- The quality of the target audience identified. The adequacy of the specific plans, activities,

and coordination for the proposed COEC, particularly with respect to their relevance to the Center's defined target audience.

- The overall importance of the Core to activities in the Center.

- The adequacy and composition of the Stakeholder Advisory Board. The contribution of this group in making administrative decisions.

- Whether outreach and educational programs will be implemented to increase awareness and understanding of the environmental health research being conducted at the Center.

- Whether the COEC is a logical outgrowth of the focus of the Center.

For competing continuation applications, the following additional criteria will be included.

- The past progress of the Center in the development of an effective COEC, and the impact that the Center has had on the local community.

X. NIEHS CONTACTS

Programmatic inquires.

Questions about EHS Core Center Grants should be addressed to:

Leslie Reinlib, PhD
Susceptibility and Population Health Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-21 111
79 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-4998
Fax: (919) 316-4606
E-mail: reinlib@niehs.nih.gov

Grants Management inquires.

Questions regarding fiscal matters should be addressed to:

Dorothy Duke
Chief, Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
79 T. W. Alexander Drive
Research Triangle Park, North Carolina 27709
Telephone: (919) 541-2749
Fax: (919) 541-2860
E-mail: duke3@niehs.nih.gov